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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,663	01/23/2002	Erik H.F. Wong	28341/6248.8	7737

4743 7590 10/22/2004

MARSHALL, GERSTEIN & BORUN LLP
6300 SEARS TOWER
233 S. WACKER DRIVE
CHICAGO, IL 60606

EXAMINER

FAY, ZOHREH A

ART UNIT PAPER NUMBER

1614

DATE MAILED: 10/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055,663

Applicant(s)

WONG ET AL.

Examiner

Zohreh Fay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17,32-37,39-51,54,56 and 57 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17,32-37,39-51,54,56 and 57 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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Claims 1-17, 32-37, 39-51, ~~and~~ 54, 56 and 57 are presented for examination.

The amendments and remarks filed on have been received and entered.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The following precedent is believed relevant to the instant case.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1968 (Fed. Cir. 1997), cert. Denied, 523 U.S. 1089, 118 S.Ct. 1548 (1998), hold that an adequate written description requires a precise definition, such as by structure, formula, chemical name, or physical properties, "not a mere wish or plan for obtaining the claimed chemical invention." Eli Lilly, 119 F. 3d at 1566. The Federal Circuit has adopted the standard set forth in the Patent and Trademark Office ("PTO") guidelines for Examination of Patent Applications under the 35 U.S.C. 112. "Written Description" requirement ("Guidelines"). 66 Fed Reg. 1099 (Jan.5, 2001), which state that the written description requirement can be met by "showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics," including, *inter alia* functional characteristics when coupled with a known or disclosed correlation

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between function and structure "Enzo biochem, inc.v.Gen-probe inc., 296 F.3d, 316, 1324-25 (Fed. Cir 2002) (quoting guideline, 66 Fed. Reg. At 1106 (emphasis added). Moreover, although Eli Lilly and Enzo were decided within the factual context of DNA sequences, this does not preclude extending the reasoning of those cases to chemical structure in general. Univ. of Rochester V. G.D. searle & co., 249 F.supp.2d 216, 225 (W.D.N.Y. 2003).

Applying the reasoning of the above-cited case law to facts at hand, the instant specification fails to provide an adequate written description of suitable compounds having a pharmaceutical selectivity of serotonin (Ki)/norepinephrine (k1) of at least about 5000. The specification describes only a limited number of such agents. The instant claims generally recite a compound having a pharmaceutical selectivity of serotonin (Ki)/norepinephrine (Ki) of at least about 5000. When functional claims are drawn this broadly, they are inclusive of any compound having selectivity of serotonin (ki)/norepinephrine (ki) of at least 5000, which can be small molecules, peptides, peptide mimetics or RNA-DNA based structures. The instant specification quite simply, discloses a few compounds within the scope of the claimed language. As such, it cannot possibly provide any direction for using any peptides, peptide mimetics, or RNA-DNA based structure; no identifying characteristics of any kind, e.g. sequences, are provided. Accordingly, the instant specification fails to provide an adequate written description.

Claims 1-17, 32-37, 39-51 and 54-57 are rejected under 35 U.S.C. 103 as being unpatentable over applicant's submitted references U.S. Patent 5,281,624 (Gehlert et

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al.) or 5,441,985 (Foreman), each in view of Dostert et al. for the reasons set forth on pages 3 and 4 of the office action of march 26, 2003.

Applicant's arguments and remarks have been carefully considered, but are not deemed to be persuasive. The prior art teaches that tricyclic anti-depressant compounds with norepinephrine reuptake inhibitory activity have been previously used for the treatment of lower urinary tract disorders. The prior art also makes clear that reboxetine is a tricyclic anti-depressant having norepinephrine reuptake inhibitory activity. Although, the prior art raises the question of the possibility of the involvement of other mechanism in treating urinary incontinence, but the inhibition of norepinephrine reuptake in treating urinary incontinence is acknowledged by the prior art. Thus, the substitution of one norepineprine reuptake inhibitor for another would have been obvious to a person skilled in the art in the absence of evidence to the contrary. Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 1-17, 32-37, 39-41, 44-51, 54, 56 and 57 are properly rejected under 35 U.S.C. 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (571) 272-0573. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z.F

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10/055,663
CLASS 1200

John F. Fay